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EXAMINER				
NAFF, DAVID M				
ART UNIT		PAPER NUMBER		
1657				
NOTIFICATION DATE		DELIVERY MODE		
10/30/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

# Office Action Summary

**Application No.**

10/087,699

**Applicant(s)**

CHENG ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 5, 6, 10, 11, 15, 16, 20 and 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 11, 15, 16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, 10 and 27-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been  
5 timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/08 has been entered.

An amendment of 8/27/08 amended claims 1, 3, 5, 10, 11, 15, 20, 27, 28 and 31, added new claims 32-38, and canceled claims 4, 8, 9, 13, 14, 18, 19, 21, 22 and 24-26. Claims 2, 7,  
12, 17 and 23 have been previously canceled.

10 Claims in the application are 1, 3, 5, 6, 10, 11, 15, 16, 20 and 27-38.

Claims 11, 15, 16 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/15/04.

Claims examined on the merits are 1, 3, 5, 6, 10 and 27-38.

### 15 ***Claim Objections***

Claims 10 and 27 are objected to because of the following informalities: claim 10 depends on canceled claim 9, and claim 27 depends on canceled claim 2. Appropriate correction is required.

### ***Specification***

20 The disclosure is objected to because of the following informalities: at page 3, line 5, the sorghum liquor waste remaining after two distillations of fermented sorghum is disclosed as containing components including 4-7% crude lipids and 20% lipids. How the sorghum liquor waste can contain 20% lipids when containing 4-7% crude lipids is unclear. If an error, the 20%

lipids should be deleted. If not an error, clarification should be provided how the sorghum liquor contains both 4-7% crude lipids and 20% lipids.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10

Claims 1, 3, 5, 6, 10 and 27-38 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for increasing thermostability of a protein when the protein is an enzyme selected from the group consisting of cellulase,  $\alpha$ -amylase and phytase, the sorghum liquor waste remaining after two distillations of fermented sorghum

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contains 10-13% crude starch, 14-22% crude proteins, 4-7% crude lipids, 17-21% crude fibers and 4-46% crude ash, and the enzyme is admixed with the sorghum liquor waste at a ratio of 1:2-10 (v/w) (specification discloses a ratio of 1:2 (v/w) (page 3 line 21) and 1:10 (v/w) (page 4, line 16 and page 5, line 7)), does not reasonably provide enablement for increasing

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thermostability of any thermolabile protein by providing a composition containing the protein admixed in any amount with any sorghum liquor waste remaining after two distillations of fermented sorghum. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims.

25

The claims encompass compositions substantially different than prepared in Examples 1-3 that provide increased thermostability. Due to unpredictability in the art, it cannot be predicted that increased thermostability as shown by the examples will result when any thermolabile protein is admixed in any amount with any sorghum liquor waste remaining after two distillations

of fermented sorghum. Different proteins have different structures and physical and chemical properties which result in the proteins reacting differently to conditions the proteins are exposed. It cannot be predicted that conditions which protect one protein against thermal denaturing will protect a different protein, and/or that conditions which protect a protein against thermal

5 denaturing can be substantially altered and still protect the protein. This unpredictability is supported by Cole (4,320,151) disclosing not being able to protect an enzyme against thermal denaturation below 40% sucrose (col 5, lines 5-7), and in Table 2 (bridging cols 9 and 10) showing varying protection including no protection when using different sugars at different concentrations and temperatures, and by Rohrbach et al (4,415,656) disclosing the

10 unpredictability of pressure stabilizing amyloglucosidase against thermal denaturation (col 2, lines 41-47). Unpredictability is further indicated by De Rosier et al (6,294,365) disclosing that combining enzymes with a stabilizing mixture may not alone be sufficient to confer stability (col 1, lines 56-57) and Rho et al (5,108,746) disclosing enzyme compositions that resulted in an unpredictable increase in shelf life or stability (col 8, lines 35-40), and Crossin (4,661,287)

15 disclosing an enzymatic liquid detergent composition where action of a component to stabilize and prevent deterioration of an enzyme was considered unpredictable and unexpected. It is clear from the above cited patents that it is unpredictable whether a particular condition will stabilize a specific enzyme against thermal denaturation, and it cannot predicted whether conditions and proteins substantially different than used in Examples 1-3 will result in the

20 increase in thermal stability obtained in the examples.

***Claim Rejections - 35 USC § 112***

Claims 1, 3, 5, 6, 10 and 27-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When using a sorghum liquor waste remaining after two distillations of fermented sorghum, the specification discloses (page 3, lines 3-6) the sorghum liquor waste containing 10-13% crude starch, 14-22% crude proteins, 4-7% crude lipids, 17-21% crude fibers and 4-46% crude ash. Support is not found for a sorghum liquor waste remaining after two distillations not containing 10-13% crude starch, 14-22% crude proteins, 4-7% crude lipids, 17-21% crude fibers and 4-46% crude ash. Additionally, support is not found in the specification for the sorghum liquor waste containing 14-22% crude protein, 17-21% crude fiber and 4-46% ash as in claims 5, 10 and 31, without also containing 10-13% crude starch and 4-7% crude lipids disclosed in the specification as also present. The specification fails to contain support for arbitrarily omitting components disclosed as being contained by the sorghum liquor waste remaining after two distillations.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 6, 10 and 27-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 1 and where recited in any other claim, "thermolabile protein" is uncertain as to meaning and scope. Any protein is thermolabile if exposed to high enough temperature, and proteins thermolabile and not thermolabile will be uncertain within the scope of the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later  
15 invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 6, 10 and 27-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunnerman et al (4,613,339) in view of Knap et al (6,558,693) and Morgan et al (6,132,716).

20 The claims are drawn to a composition comprising a thermolabile protein admixed with sorghum liquor waste, which remains after two distillations of fermented sorghum.

Gunnerman et al disclose fermenting a sugar-containing fluid from sorghum, and distilling to obtain ethanol. A residue known as stillage from the distillation is used as animal feed (col 4, lines 46-49).

25 Knap et al disclose an animal feed additive containing a galactanase and one or more other feed enhancing enzymes selected from a group including phytase and cellulase (col 2, lines 39-46). The feed to which the additive is added may contain sorghum (col 4, line 62).

Morgan et al disclose a feed additive containing a thermostable xylanase and one or more other enzymes selected from a group including phytase and  $\alpha$ -amylase.

When using stillage as animal feed as suggested by Gunnerman et al, it would have been obvious to add feed enhancing enzymes to the stillage as suggested by Knap et al and Morgan et al to obtain the function of the enzymes to improve the stillage as a feed. The stillage is inherently a sorghum liquor waste from distillation. Using sorghum waste from two distillations would be obvious to provide more stillage as animal feed. The feed enhancing enzymes suggested by Knap et al and Morgan et al are inherently thermolabile. Increasing enzyme thermostability as disclosed in the present specification will be inherent when adding the feed enhancing enzymes suggested by Knap et al and Morgan et al to the animal feed stillage of Gunnerman et al. The conditions of dependent claims would have been matters of obvious choice within the ordinary skill of the art. Knap et al and Morgan et al suggest cellulase and  $\alpha$ -amylase required by dependent claims 32-35, 37 and 38 as feed enhancing enzymes, and using these enzymes as the feed enhancing enzymes would have been obvious. The stillage of Gunnerman et al inherently has a composition as required by dependent claims 5, 10 and 31. Providing the stillage containing the feed enhancing enzymes in dry form would have been obvious to preserve the stillage and enzymes, and reduce the cost of transportation. Having the enzyme-containing stillage ground and sieved as in depending claims 27 and 28 would have been obvious to obtain a dry composition of desired uniform particle sizes.

### ***Response to Arguments***

Arguments traversing the previous rejections under 35 USC 112 and 103 are moot since these rejections have been withdrawn, and replaced with new rejections under 25 USC 112 and 103.

Claim 1 would be allowable if amended to read as follows ---



1. A composition providing increased enzyme thermostability comprising an enzyme selected from the group consisting of phytase, cellulase and  $\alpha$ -amylase admixed with a sorghum liquor waste remaining after two distillations of fermented sorghum, wherein said sorghum liquor waste contains 10-13% crude starch, 14-22% crude proteins, 4-7% crude lipids, 17-21% crude fibers and 4-46% crude ash, and said enzyme is admixed with said sorghum liquor waste at a ratio of 1:2-10 (v/w). ---.

With these changes to claim 1, dependent claims should be amended as follows:

cancel claims 5, 6, 10, 30, 31 and 34-38, make claims 32 and 33 dependent on claim 1, and In line 2 of claim 27, cancel "the protein" and insert --- said enzyme ---.

- 10 Claims 11, 15, 16 and 20 drawn to a method of enhancing protein thermostability can be rejoined only if the claims contain all limitations that result in the allowance of the claims drawn to the composition, and the claims are free of rejection under 35 USC 112.

### ***Conclusion***

- Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

DMN  
10/24/08